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Rt Hon Patricia Hewitt MP
Secretary of State for Health
The Department of Health
Richmond House
79 Whitehall
London SW1A 2NL

20th September 2005

Dear Secretary of State,

Safety of Magnetic Resonance Imaging (MRI) Equipment

The EU Physical Agents (EMF) Directive 2004/40/EC, which seeks to define safe levels for equipment operators' exposure to electromagnetic fields (EMF), was published last year on 29th April. The Directive puts limits on the exposure of operating staff (including those maintaining equipment) from zero frequency up to 300GHz. The limits proposed are huge extrapolations from largely hypothetical possible conditions and are an over-cautious interpretation of very limited experimental data. The Directive has consequences for clinical magnetic resonance imaging (MRI) which, while apparently unintended, are potentially disastrous.

We are writing to urge you to support a change in the Directive, which has not been forthcoming despite the efforts of the medical community, and in the meantime to seek a postponement of its implementation in order to arrange the necessary and relatively modest research that has not yet been undertaken by the national advisory agencies, but which will probably result in quite different permitted levels in the important and relevant areas.

The Directive's proposed exposure limits threaten our ability to diagnose and treat many patients, particularly those who are frail, anxious or anaesthetised. It will end interventional MRI, with the loss of well-documented improved outcome for tumour, cardiac and other patients. Parents and nurses will be unable to comfort children during scans. We will have to rely more, instead of less, on X-ray examinations of paediatric patients (for which their age is regarded as an absolute contraindication). This carries unwanted side-effects for many patients for whom injection of the X-ray contrast agents is much more traumatic than that of the equivalent MRI agents. Furthermore, since there is a known mortality rate associated with X-ray agents, patient's lives are being put at risk to a significant extent.

The Directive will reduce the value of recent NHS investment, damage British industry (where we are the world leader in design and manufacture of the magnets that are at the core of all MRI systems) and undermine important clinical research. Even the Health and Safety Executive, in

their assessment of the Directive, could find no justification for the damage it might do without a balancing improvement in the health and safety of those exposed to the various radiations.

As researchers, clinicians, and employers, we are particularly concerned that these consequences will arise from legislation that has no apparent benefit to staff or patients. MR scanners are already designed to protect patients – and as a consequence staff – from known EMF hazards, such as heating effects due to radiofrequency (RF) radiation: there have been no known harmful effects of staff exposure to low frequency EMF, such as is used in MRI systems. Contrary to the inference of the Directive, the physics and engineering demands of MRI are such that scanners cannot be adapted to conform to the proposed European regulations. The large, installed base of clinical MRI scanners in this country would be restricted in its utility, and, in some instances, would have to be shut down.

Cautionary use of MR equipment is already standard. The very first set of MRI clinical guidelines was produced by NRPB in Britain; the lead signatory of this letter was part of the advisory panel involved in their formulation. These guidelines were simple and unambiguous, and served patients and staff well.

In spite of repeated requests to reinvestigate the limits, the National Radiological Protection Board (now HPA) has not responded. The peer reviewed literature does not contain sufficient data for an assessment. It should be noted that national agencies elsewhere refer instead to the data acquired in routine clinical activities. However, in Europe, we are in the odd situation of having to introduce poorly justified and damaging measures because our national agencies show little interest in such further investigations. We believe that the research programme needed to provide complete justification for a relaxation of the limits set in the Directive can be completed in about two years at relatively modest cost. This will involve the funding of research scientists in major UK academic institutions, who will have access to the records possessed by NRPB in this country, and FDA in the USA, and will investigate possible bioeffects of MRI.

In conclusion, we ask that the Government will speedily convene a group to investigate the damage that implementation of the Physical Agents Directive will inflict on clinical MRI. We ask that you press for amendment of the Directive to prevent its adverse impact on MRI. Finally, we ask that, in view of the profound implications of the Directive for healthcare, clinical research and industry, you will delay drafting UK legislation by two years in favour of supporting the proper research.

We trust that you will give this matter the urgent attention that it deserves.

Yours sincerely

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